CLAIMS

What is claimed is:

1. A method of preventing or treating a disease or adverse condition affecting the gastrointestinal tract comprising orally administering to a mammal
   a. a therapeutically effective amount of a prodrug of a proton pump inhibitor, and
   b. an effective amount of a trefoil family factor peptide, a mucoadhesive agent, or a combination thereof.

2. The method of claim 1 wherein the prodrug has a membrane permeability and the proton pump inhibitor has a membrane permeability, wherein the membrane permeability of the proton pump inhibitor is more than twice the membrane permeability of the prodrug.

3. The method of claim 2 wherein the membrane permeability of the proton pump inhibitor is more than 10 times the membrane permeability of the prodrug.

4. The method of claim 2 wherein the membrane permeability of the proton pump inhibitor is more than 100 times the membrane permeability of the prodrug.

5. The method of claim 2 wherein the membrane permeability of the proton pump inhibitor is more than 150 times the membrane permeability of the prodrug.

6. The method of claim 1 wherein the prodrug is converted to a proton pump inhibitor selected from the group consisting of omeprazole, esomeprazole, lansoprazole, pantoprazole, and rabeprazole after oral administration.

7. The method of claim 1 wherein the prodrug is converted to omeprazole after oral administration.

8. The method of claim 1 wherein the prodrug is converted to lansoprazole after oral administration.

9. The method of claim 1 wherein the prodrug comprises a sulfonyl moiety, and wherein said prodrug is converted to omeprazole after oral administration.

10. The method of claim 1 wherein the prodrug comprises a sulfonyl moiety and wherein said prodrug is converted to lansoprazole after oral administration.

11. The method of claim 1 wherein a trefoil factor family peptide is administered orally to said mammal.

12. The method of claim 1 wherein a mucoadhesive is administered orally to said mammal.

13. The method of claim 1 wherein a mucoadhesive is administered orally to said mammal, said mucoadhesive comprising Tamarind seed polysaccharide.

14. The method of claim 1 wherein a trefoil factor family peptide and a mucoadhesive are administered orally to said mammal.

15. The method of claim 1 wherein a trefoil factor family peptide and a mucoadhesive are administered orally to said mammal, and wherein said mucoadhesive comprises a polysaccharide.

16. The method of claim 1 wherein a trefoil factor family peptide and a mucoadhesive are administered orally to said mammal, and wherein said mucoadhesive comprises Tamarind seed polysaccharide.

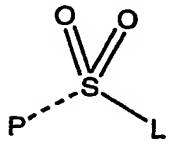
17. A composition comprising

a prodrug of a proton pump inhibitor, and

a trefoil family factor peptide, a mucoadhesive component, or a combination thereof,

wherein said composition is suitable for use in a pharmaceutical dosage form.

18. The composition of claim 17 wherein said prodrug comprises



or a pharmaceutically acceptable salt thereof;

wherein

the dashed line indicates a bond that is broken systemically in said mammal;

P is a moiety that is converted systemically to a proton pump inhibitor as a result of cleavage of the bond indicated by the dashed line; and

L is a moiety which comprises a carboxylic acid.

19. The composition of claim 18 wherein L comprises a phenyl moiety.

20. The composition of claim 18 wherein P is converted systemically to a proton pump inhibitor selected from the group consisting of omeprazole, esomeprazole, lansoprazole, pantoprazole, and rabeprazole.

21. The composition of claim 18 wherein P is converted systemically to omeprazole.

22. The composition of claim 18 wherein P is converted systemically to lansoprazole.

23. The composition of claim 17 which comprises a mucoadhesive component.

24. The composition of claim 17 which comprises Tamarind seed polysaccharide.

25. The composition of claim 17 which comprises a trefoil factor family peptide.

26. The composition of claim 17 which comprises a mucoadhesive component and a trefoil factor family peptide.

27. The composition of claim 17 which comprises Tamarind seed polysaccharide and a trefoil factor family peptide.

28. The composition of claim 17 which comprises Tamarind seed polysaccharide, a trefoil factor family peptide, and further comprises a proton pump inhibitor.

29. The composition of claim 17 which further comprises a proton pump inhibitor.

30. The composition of claim 17 which comprises a mixture of prodrugs of a proton pump inhibitor.

31. The composition of claim 17 which comprises a mixture of two prodrugs of a proton pump inhibitor, said prodrugs having a membrane permeability ratio of from 2 to 1000.

32. The composition of claim 17 which comprises a mixture of two prodrugs of a proton pump inhibitor, said prodrugs having a membrane permeability ratio of from 10 to 500.

33. The composition of claim 17 which comprises a mixture of two prodrugs of a proton pump inhibitor, said prodrugs having a membrane permeability ratio of from 100 to 500.

34. An oral dosage form comprising a therapeutically active component and a trefoil factor family peptide, wherein said therapeutically active component is selected from the group consisting of proton pump inhibitors, prodrugs of proton pump inhibitors, and combinations thereof.

35. The dosage form of claim 34, wherein the therapeutically active component is omeprazole.

36. The dosage form of claim 34 wherein the therapeutically active component is esomeprazole.

37. The dosage form of claim 34 wherein the therapeutically active component is lansoprazole.

38. The dosage form of claim 34 wherein the therapeutically active component is pantoprazole.

39. The dosage form of claim 34 wherein the therapeutically active component is rabeprazole.

40. The dosage form of claim 34 wherein the therapeutically active component comprises a prodrug of a proton pump inhibitor.

41. The dosage form of claim 34 wherein the therapeutically active component comprises both a proton pump inhibitor and a prodrug of a proton pump inhibitor.

42. The dosage form of claim 34 wherein the therapeutically active component comprises a prodrug having a sulfonyl leaving group.

43. The dosage form of claim 34 wherein the therapeutically active component comprises a prodrug having a sulfonyl leaving group, wherein said sulfonyl leaving group also comprises a carboxylic acid moiety or a pharmaceutically acceptable salt thereof.

44. The dosage form of claim 34 wherein the therapeutically active component is a single compound, said compound being a proton pump inhibitor or a prodrug of a proton pump inhibitor, which has a membrane permeability which is less than 1.4×10^{-5} cm/sec.

45. The dosage form of claim 34 wherein the therapeutically active component is a single compound, said compound being a proton pump inhibitor or a prodrug of a proton pump inhibitor, which has a membrane permeability which is less than 1×10^{-6} cm/sec.

46. The dosage form of claim 34 wherein the therapeutically active component is a single compound, said compound being a proton pump inhibitor or a prodrug of a proton pump inhibitor, which has a membrane permeability which is less than 5×10^{-7} cm/sec.

47. The dosage form of claim 34 wherein the therapeutically active component is a single compound, said compound being a proton pump inhibitor or a prodrug of a proton pump inhibitor which has a membrane permeability which is less than 1×10^{-7} cm/sec.

48. The dosage form of claim 34 wherein the therapeutically active component is a single compound, said compound being a proton pump inhibitor or a prodrug of a proton pump inhibitor which has a membrane permeability which is less than 5×10^{-8} cm/sec.

49. The dosage form of claim 34 wherein the trefoil factor family peptide is TFF1, TFF2, or TFF3.

50. The dosage form of claim 34 wherein the trefoil factor family peptide is TFF1 or TFF2.

51. The dosage form of claim 34 wherein the trefoil factor family peptide is TFF1.

52. The dosage form of claim 34 wherein the trefoil factor family peptide is TFF2.

53. The dosage form of claim 34 which further comprises a mucoadhesive.

54. The dosage form of claim 34 which further comprises Tamarind seed polysaccharide.

55. A method of preventing or treating a disease or adverse condition comprising administering directly into a gastrointestinal tract of a mammal an effective amount of a therapeutically active agent, and
a therapeutically effective amount of a trefoil factor family peptide, wherein

said therapeutically active agent comprises a compound which, when administered orally, results in inhibition of the gastric H,K-ATPase enzyme, and

wherein said disease or condition affects the gastrointestinal tract.

56. The method of claim 55 wherein the therapeutically active agent comprises a benzimidazole derivative.

57. The method of claim 55 wherein the therapeutically active agent comprises a benzimidazole derivative and a biological leaving group.

58. The method of claim 55 wherein the therapeutically active agent comprises a benzimidazole derivative and a biological leaving group with a sulfonyl moiety.

59. The method of claim 55 wherein the therapeutically active agent comprises a benzimidazole derivative and a biological leaving group with a sulfonyl moiety, said biological leaving group further comprising a carboxylic acid or a pharmaceutically acceptable salt thereof.

60. The method of claim 55 wherein the therapeutically active agent is a proton pump inhibitor or a salt or prodrug thereof, wherein said proton pump inhibitor is selected from the group consisting of omeprazole, esomeprazole, lansoprazole, pantoprazole, and rabeprazole.

61. The method of claim 55 wherein the therapeutically active agent is a prodrug of a proton pump inhibitor wherein said proton pump inhibitor is selected from the group consisting of omeprazole, esomeprazole, lansoprazole, pantoprazole, and rabeprazole.

62. The method of claim 55 wherein the therapeutically active agent comprises a mixture of a proton pump inhibitor and its prodrug.

63. The method of claim 55 wherein the trefoil family factor peptide is TFF1.

64. The method of claim 55 wherein the trefoil family factor peptide is TFF2.

65. The method of claim 55 wherein the trefoil family factor peptide is TFF3.

66. The method of claim 55 wherein a mucoadhesive is also administered to said mammal.

67. The method of claim 55 wherein Tamarind seed polysaccharide is also administered to said mammal.

68. The method of claim 55 wherein the therapeutically active agent comprises a mixture of a proton pump inhibitor and a prodrug of said proton pump inhibitor, said proton pump inhibitor having a membrane permeability and said prodrug having a membrane permeability, wherein the membrane permeability of the proton pump inhibitor is more than 10 times the membrane permeability of the prodrug.

69. The method of claim 68 wherein the membrane permeability of the proton pump inhibitor is more than 100 times that of the prodrug.

70. The method of claim 68 wherein the membrane permeability of the proton pump inhibitor is more than 150 times that of the prodrug.